

PCT/AU99/01108

Dose (mg)

TABLES

No. of doses	Resn (wk)
1	10
2	10
3	10
4	10
5	10
6	10
7	10
8	10
9	10
10	10
11	10
12	10
13	10
14	10
15	10
16	10
17	10
18	10
19	10
20	10
21	10
22	10
23	10
24	10
25	10
26	10
27	10
28	10
29	10
30	10
31	10
32	10
33	10
34	10
35	10
36	10
37	10
38	10
39	10
40	10
41	10
42	10
43	10
44	10
45	10
46	10
47	10
48	10
49	10
50	10
51	10
52	10
53	10
54	10
55	10
56	10
57	10
58	10
59	10
60	10
61	10
62	10
63	10
64	10
65	10
66	10
67	10
68	10
69	10
70	10
71	10
72	10
73	10
74	10
75	10
76	10
77	10
78	10
79	10
80	10
81	10
82	10
83	10
84	10
85	10
86	10
87	10
88	10
89	10
90	10
91	10
92	10
93	10
94	10
95	10
96	10
97	10
98	10
99	10
100	10

DTM VLP VLP
Hist Ab, Pre Ab Post

Age	No. of Sex	Site	Time	Area
			months	mm ²

TABLE 1

ID	Age Sex	No. of Warts	Site	Time multi	Area mm ²	Pror. Rx. No.	Dose (mg)	No. of doses	Ratio (%)	DTM Histo	DTM Histo	VLP Ab Pre	VLP Ab Post
ZLY	22F	4	vulva	1	60	0	1	3	6	3	4	.103	.283
LPP	41F	2	vulva	3	100	2	1	3	4	3	2	.018	.083
LLL	34F	2	multi	1	125	0	1	3	2	1	2	.054	.082
YXR	50F	2	vulva	-	200	0	1	3	1	3	2	.034	.043
WY	24F	3	cervix	5	240	3	1	3	3	3	4	.197	.301
XAQ	32F	4	multi	2	475	2	1	3	5	3	5	.032	.074
FPY	36F	5	vulva	3	500	2	1	3	7	3	4	.041	.128
QLH	18F	8	vulva	3	600	3	1	3	8	3	2	.068	.235
RYL	41F	1	vulva	20	50	0	5	3	4	3	4	.033	.104
ZJH	27M	2	penis	1	50	0	5	3	10	2	4	.003	.208
ZCY	24F	1	anus	-	125	1	5	3	9	2	Nd	.105	.404
SYF	27F	2	vulva	1	130	0	5	3	9	2	3	.131	.348
PML	43F	3	multi	1	165	2	5	3	8	3	4	.075	.276
JHF	20F	5	multi	2	240	2	5	3	20+	nd	Nd	-.018	.156
XJF	23F	5	vulva	1	500	0	5	3	6	1	4	.010	.274
LCL	35F	12	multi	1	750	0	5	3	6	2	4	.100	.355
JHL	32M	2	penis	1	25	0	5	4	14	1	Nd	.009	.131

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ID	Age Sex	No. of warts	Site	Time mins	Area mm ²	Prv Rx No	Dose (µg)	No. of doses	Resn (wk)	DTH	DTH Hist	WLP Ab Pre	WLP Ab Post
WXQ	50F	1	vulva	2	900	0	5	4	20+	1	Nd	nd	Nd
ZGS	36M	3	penis	1	100	0	5	5	20	1	1	.003	.194
LXH	30F	11	multi	1	875	0	5	6	20+	3	3	-.017	.259
YMX	32F	8	vulva	2	880	1	5	8	20+	3	2	.068	.528
CLL	24F	3	vulva	1	150	1	10	3	10	2	5	.042	.361
JML	48F	1	vulva	-	250	0	10	3	4	3	2	.090	.27
WZZ	20F	5	vulva	1	250	2	10	3	10	3	3	.357	.491
JJL	39F	4	multi	1	300	0	10	3	8	3	4	.041	.327
ZXH	28F	6	multi	2	310	0	10	3	20+	3	3	.311	.420
CDY	56M	3	penis	1	40	0	10	4	8	2	Nd	-.009	.301
ZHQ	24F	5	vulva	2	100	1	10	4	10	1	1	.448	.521
HSS	23F	7	multi	3	650	2	10	5	20+	1	3	.109	.455
ZSQ	55M	4	penis	3	80	3	10	6	20	2	3	.060	.377
YQ	30F	2	multi	1	125	0	10	6	20+	1	3	.033	.119
MXV	26F	14	multi	1	180	0	10	6	20+	2	2	.080	.491
WFX	25F	8	multi	2	950	2	10	6	11	3	4	.072	.151

Substitute Sheet (Rule 26) RO/AU

Same as previous Sheet

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TABLE 2 Summary subject demographics, treatment regimes and outcome by immunization dose

Group (Dose)	Number (F:M)	Age (years: mean, range)	No. of warts at presentation (mean, range)	Area of warts at presentation (mm ² : mean, range)	Duration of warts (months: mean, range)	Past Caustery (Yes: No)	Outcome at week 20 (resolved: persistent)	Mean time to resolution (Weeks: mean, range)
All subjects	27F:6M	32(18-56)	4.5(1-14)	325(25-950)	2.4(1-20)	15:18	25:8	11.0(1-NR)
1 µg	7F:1M	31(18-50)	3.8(2-8)	287(60-600)	2.6(1-5)	5:3	8:0	4.5(1-8)
5 µg	10F:3M	32(20-50)	4.3(1-12)	368(25-900)	2.8(1-20)	4:8	9:4	12.7(4-N.R.)
10 µg	10F:2M	33(20-56)	5.2(1-14)	282(40-950)	1.6(1-3)	6:6	8:4	13.4(4-N.R.)
1	2	3	4	5	6	7	8	9

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1 = Group (Dose)

2 = Number (F:M)

3 = Age (years: mean, range)

4 = No. of warts at presentation (mean, range)

5 = Area of warts at presentation (mm²: mean, range)

6 = Duration of warts (months: mean, range)

7 = Past Caustery (Yes: No)

8 = Outcome at week 20 (resolved: persistent)

9 = Mean time to resolution (Weeks: mean, range)

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TABLE 3 Predictors of wart resolution during the period of observation

	Resolved (n=25)	Not resolved (n=8)	P
Age	33.4 ± 2.2	29.9 ± 3.2	NS
Duration of warts (months)	2.5 ± 0.8	1.8 ± 0.4	NS
No. of warts at entry	3.8 ± 0.5	6.8 ± 1.5	P=0.019
Wart area at entry (mm ²)	252 ± 48	520 ± 120	P=0.021
DTH reaction to VLPs ^A	2.32 ± 0.16	2.0 ± 0.37	NS
VLP antibody pre-immunization ^B	0.084 ± 0.021	0.080 ± 0.042	NS
VLP antibody post immunization	0.253 ± 0.026	0.347 ± 0.063	NS